Potential Protection of Human Subjects Issues in Accessions Research

Mark E. Cohen, PhD
IRB Chair
Naval Institute for Dental and Biomedical Research
mecohen@nidbr.med.navy.mil

I originally approached this presentation from the perspective of IRB policies as they would be applied in biomedical research. There, virtually all research requires some level of IRB oversight.

After some consideration of what 'Accessions Training Research' involves, it would seem that the relevant issues would have already been addressed and resolved somewhere along the Naval Service Training Command chain. And this research might already have been determined, by regulation or policy, as not invoking any protection of human subjects issues. (Is this true?)

Regardless, this presentation may be useful for evaluating research that crosses

Is the accessions‘research’ human subjects research requiring IRB oversight?

The guiding document is *Title 32 CFR 219* (Protection of Human Subjects under the purview of the Office of the Secretary of Defense).

Portions of this document will be selected, rearranged, paraphrased, and summarized to focus on our particular issue.

An exclusion based on intent

Sec. 219.102 Definitions, limits research to '… a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.' A common criterion for 'generalizable' is interest in publication in the open literature. If your work is intended only for internal purposes, it is most likely not research.

Research in educational settings and surveys exempt from *32 CFR 219*

- *Sec. 219.101 To what does this policy apply?* identifies a large segment of typical accessions training research that is not research for purposes of human subjects protection and IRB oversight:
- (1) Research in educational settings involving normal educational practices including: instructional strategies, techniques, curricula, or classroom management
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior, unless subjects can be identified and identification poses risks, unless Federal statute requires that confidentiality be maintained forever

Exempt research

Federal regulations provide that certain categories of innocuous research may be exempted from formal IRB review, in order to lessen the regulatory burden without compromising the protections afforded to potential human research participants. A research effort is defined as exempt if the specific project is both minimal risk and meets the eligibility criteria for exemption.

Some PHS issues for ‘accessions research”

- Does ‘accessions’ fit into research on standard educational practices or tests?
- Could personal information from NSTC be harmful to persons’ reputation. Is confidentiality protected by statute?
- Is this for internal use only? Would NSTC staff ever contemplate publishing their research on accessions outcomes- even in a military journal?
- Is an outside institution involved (e.g., a university)? Is research for publication part of their standard expectation?

Other research exempt from *32 CFR 219*

- (3) Research involving the collection or study of existing data, documents, records, or specimens if publicly available or if the information is recorded by the investigator so that the subject cannot be identified
- Activities that, in the judgment of the department or agency head, are not covered by this policy … (has this determination been made?)

At this point we are going to switch from *Title 32 CFR 219* to flowcharts provided by the Office of Human Research Protections (OHRP), which are based on Department of Health and Human Services (HHS) regulations in *45 CFR 46*.

http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm

Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

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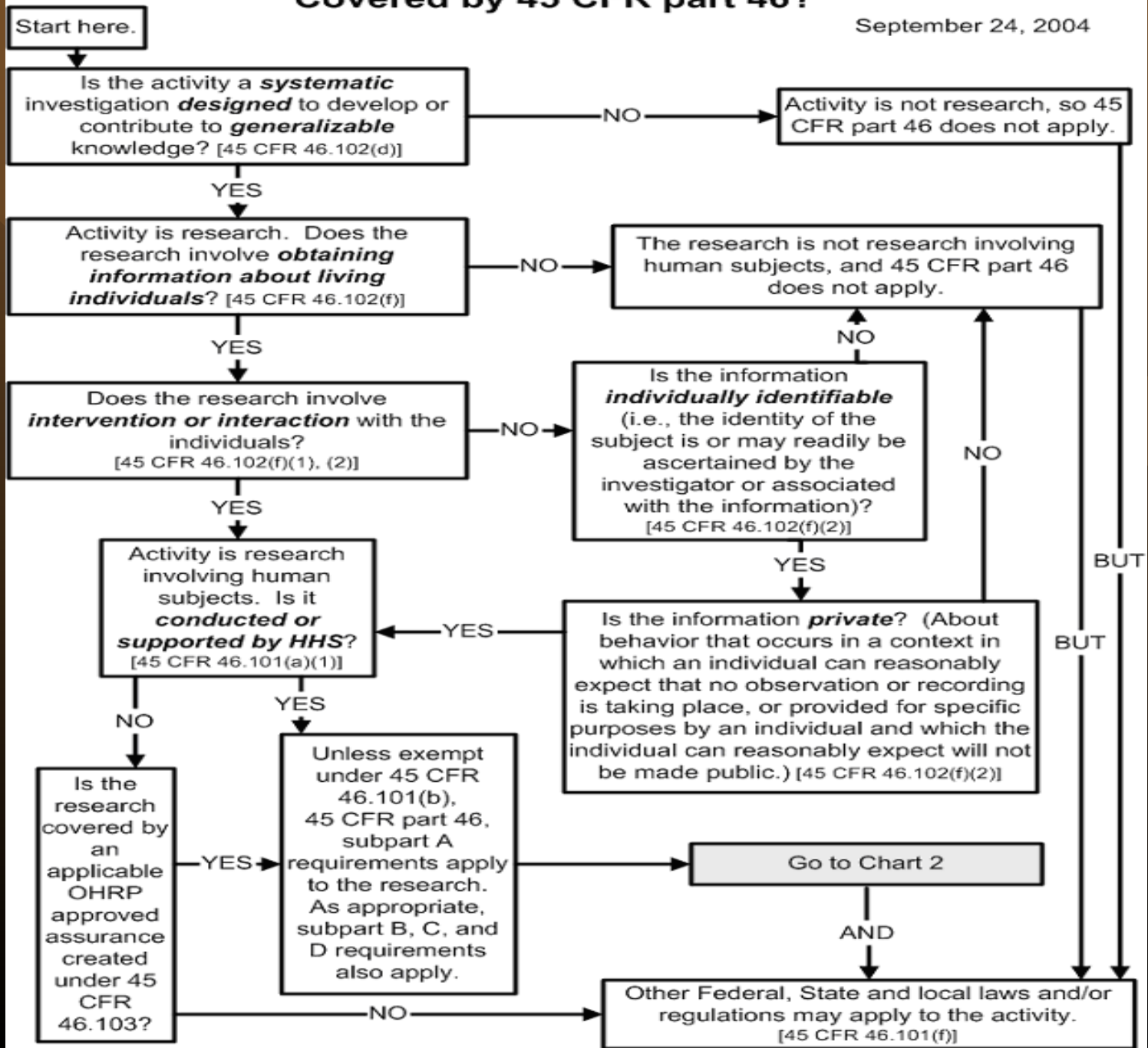
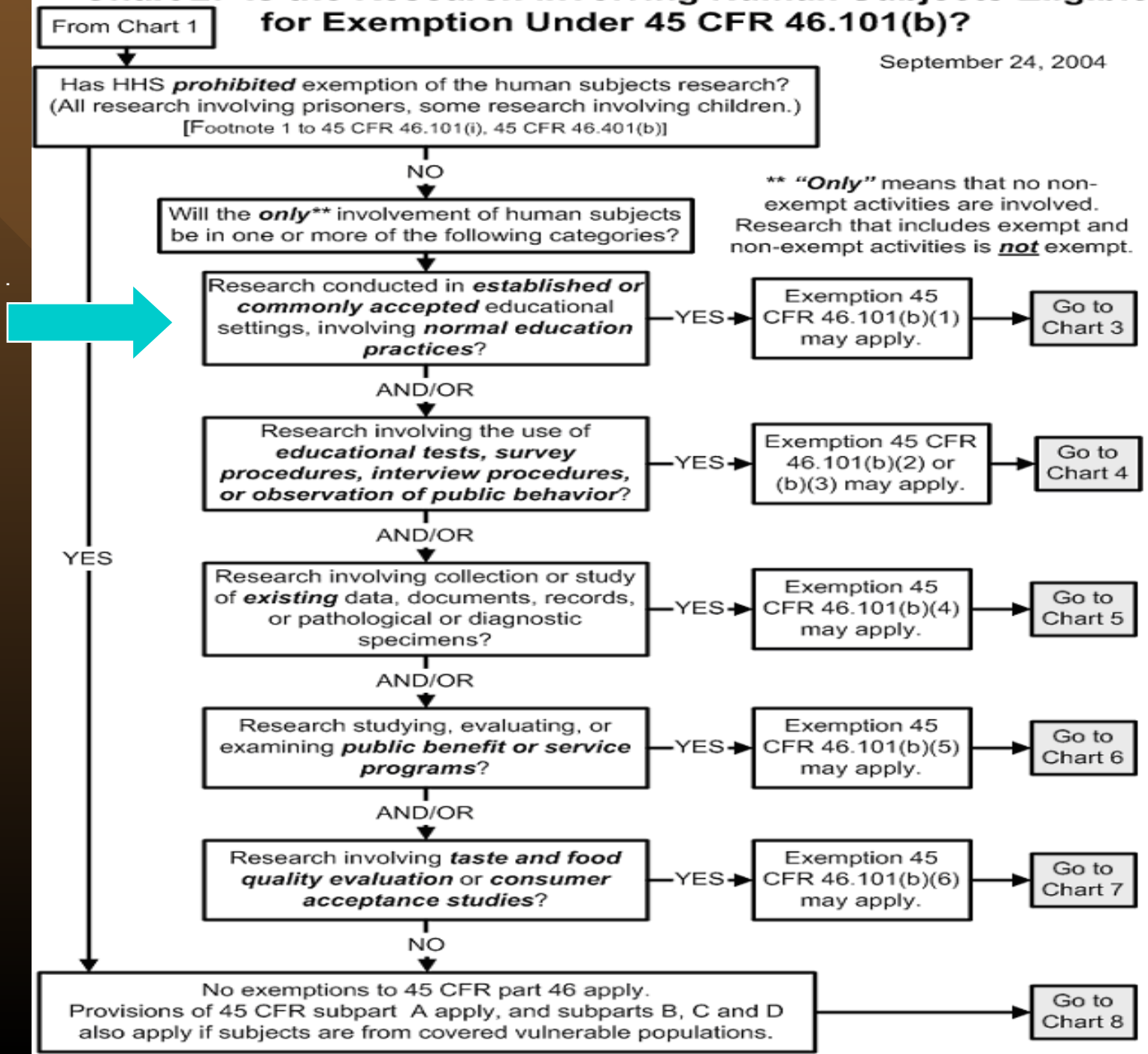

Start here.
Is the activity a *systematic* investigation *designed* to develop or contribute to *generalizable* knowledge? [45 CFR 46.102(d)]
NO
Activity is not research, so 45 CFR part 46 does not apply.
YES
Activity is research. Does the research involve *obtaining information about living individuals*? [45 CFR 46.102(f)]
NO
The research is not research involving human subjects, and 45 CFR part 46 does not apply.
YES
Does the research involve *intervention or interaction* with the individuals? [45 CFR 46.102(f)(1), (2)]
NO
Is the information *individually identifiable* (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)? [45 CFR 46.102(f)(2)]
YES
Activity is research involving human subjects. Is it *conducted or supported by HHS*? [45 CFR 46.101(a)(1)]
YES
Is the information *private*? (About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.) [45 CFR 46.102(f)(2)]
NO
YES
NO
Is the research covered by an applicable OHRP approved assurance created under 45 CFR 46.103?
YES
Unless exempt under 45 CFR 46.101(b), 45 CFR part 46, subpart A requirements apply to the research. As appropriate, subpart B, C, and D requirements also apply.
Go to Chart 2
AND
NO
Other Federal, State and local laws and/or regulations may apply to the activity. [45 CFR 46.101(f)]
BUT
BUT

Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?


From Chart 1
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Has HHS *prohibited* exemption of the human subjects research? (All research involving prisoners, some research involving children.) [Footnote 1 to 45 CFR 46.101(i), 45 CFR 46.401(b)]
NO
YES
** *"Only"* means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is ***not*** exempt.
Will the *only*** involvement of human subjects be in one or more of the following categories?
Research conducted in *established or commonly accepted* educational settings, involving *normal education practices*?
YES
Exemption 45 CFR 46.101(b)(1) may apply.
Go to Chart 3
AND/OR
Research involving the use of *educational tests, survey procedures, interview procedures, or observation of public behavior*?
YES
Exemption 45 CFR 46.101(b)(2) or (b)(3) may apply.
Go to Chart 4
AND/OR
Research involving collection or study of *existing* data, documents, records, or pathological or diagnostic specimens?
YES
Exemption 45 CFR 46.101(b)(4) may apply.
Go to Chart 5
AND/OR
Research studying, evaluating, or examining *public benefit or service programs*?
YES
Exemption 45 CFR 46.101(b)(5) may apply.
Go to Chart 6
AND/OR
Research involving *taste and food quality evaluation* or *consumer acceptance studies*?
YES
Exemption 45 CFR 46.101(b)(6) may apply.
Go to Chart 7
NO
No exemptions to 45 CFR part 46 apply. Provisions of 45 CFR subpart A apply, and subparts B, C and D also apply if subjects are from covered vulnerable populations.
Go to Chart 8

Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

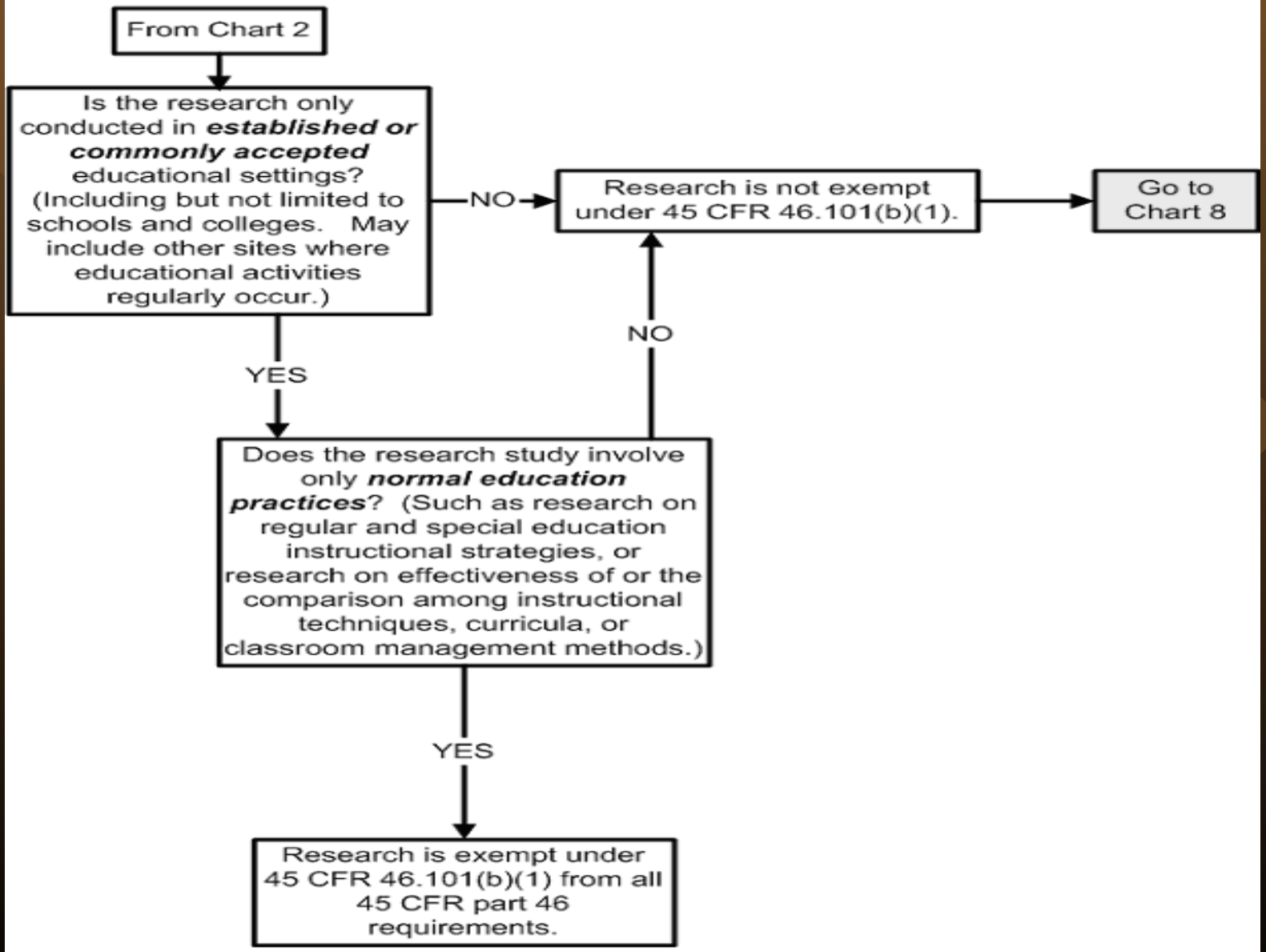
From Chart 2
Is the research only conducted in ***established or commonly accepted*** educational settings? (Including but not limited to schools and colleges. May include other sites where educational activities regularly occur.)
NO
Research is not exempt under 45 CFR 46.101(b)(1).
Go to Chart 8
YES
NO
Does the research study involve only ***normal education practices***? (Such as research on regular and special education instructional strategies, or research on effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.)
YES
Research is exempt under 45 CFR 46.101(b)(1) from all 45 CFR part 46 requirements.

Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

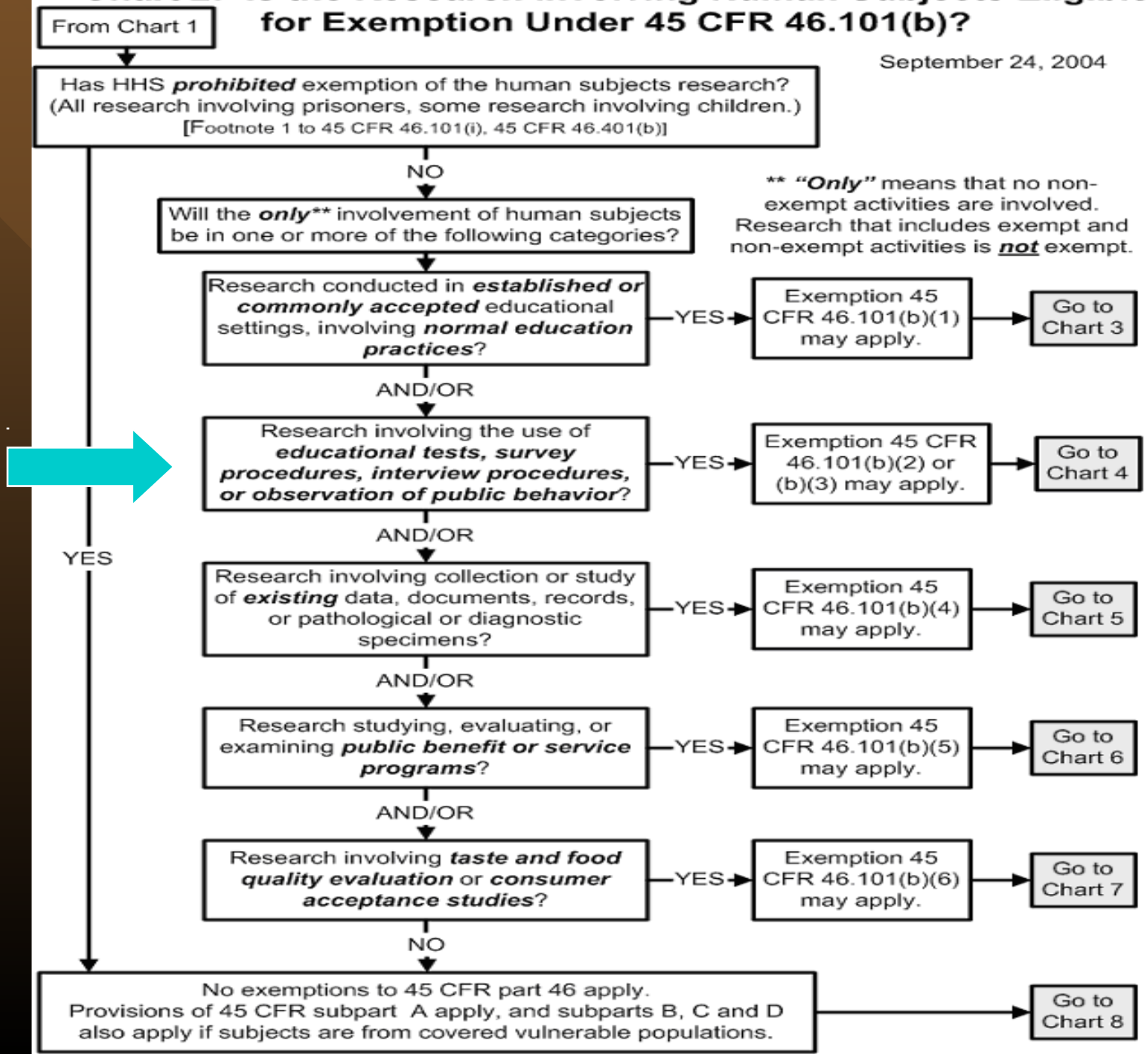
From Chart 1
September 24, 2004
Has HHS *prohibited* exemption of the human subjects research? (All research involving prisoners, some research involving children.) [Footnote 1 to 45 CFR 46.101(i), 45 CFR 46.401(b)]
NO
YES
** *"Only"* means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is ***not*** exempt.
Will the *only*** involvement of human subjects be in one or more of the following categories?
Research conducted in *established or commonly accepted* educational settings, involving *normal education practices*?
YES
Exemption 45 CFR 46.101(b)(1) may apply.
Go to Chart 3
AND/OR
Research involving the use of *educational tests, survey procedures, interview procedures, or observation of public behavior*?
YES
Exemption 45 CFR 46.101(b)(2) or (b)(3) may apply.
Go to Chart 4
AND/OR
Research involving collection or study of *existing* data, documents, records, or pathological or diagnostic specimens?
YES
Exemption 45 CFR 46.101(b)(4) may apply.
Go to Chart 5
AND/OR
Research studying, evaluating, or examining *public benefit or service programs*?
YES
Exemption 45 CFR 46.101(b)(5) may apply.
Go to Chart 6
AND/OR
Research involving *taste and food quality evaluation* or *consumer acceptance studies*?
YES
Exemption 45 CFR 46.101(b)(6) may apply.
Go to Chart 7
NO
No exemptions to 45 CFR part 46 apply. Provisions of 45 CFR subpart A apply, and subparts B, C and D also apply if subjects are from covered vulnerable populations.
Go to Chart 8

Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

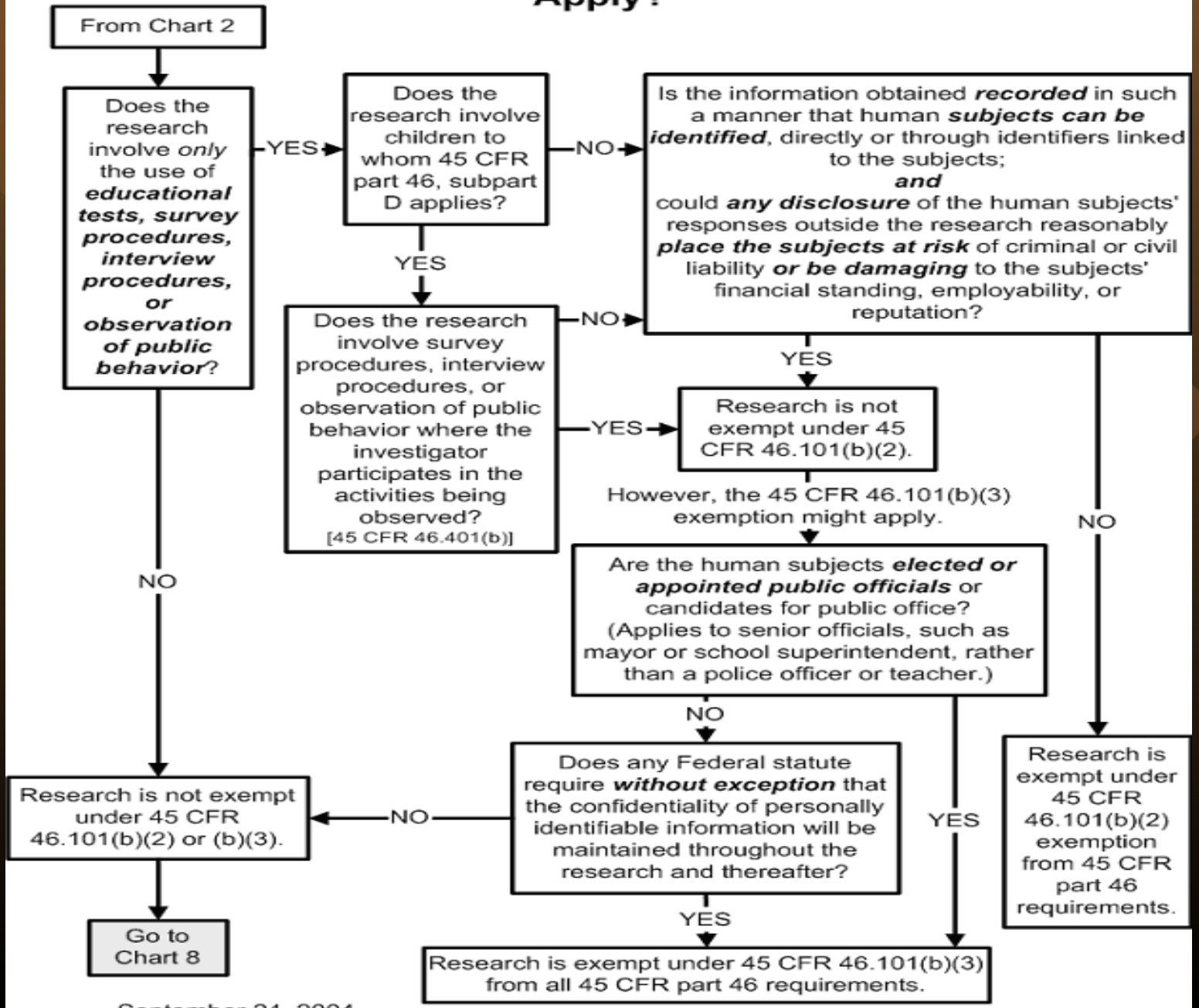
From Chart 2
Does the research involve *only* the use of ***educational tests, survey procedures, interview procedures, or observation of public behavior***?
YES
Does the research involve children to whom 45 CFR part 46, subpart D applies?
NO
Is the information obtained ***recorded*** in such a manner that human ***subjects can be identified***, directly or through identifiers linked to the subjects;
and
could ***any disclosure*** of the human subjects' responses outside the research reasonably ***place the subjects at risk*** of criminal or civil liability ***or be damaging*** to the subjects' financial standing, employability, or reputation?
YES
Does the research involve survey procedures, interview procedures, or observation of public behavior where the investigator participates in the activities being observed?
[45 CFR 46.401(b)]
NO
YES
Research is not exempt under 45 CFR 46.101(b)(2).
However, the 45 CFR 46.101(b)(3) exemption might apply.
Are the human subjects ***elected or appointed public officials*** or candidates for public office?
(Applies to senior officials, such as mayor or school superintendent, rather than a police officer or teacher.)
NO
YES
NO
Research is exempt under 45 CFR 46.101(b)(2) exemption from 45 CFR part 46 requirements.
NO
Does any Federal statute require ***without exception*** that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter?
NO
Research is not exempt under 45 CFR 46.101(b)(2) or (b)(3).
Go to Chart 8
YES
YES
Research is exempt under 45 CFR 46.101(b)(3) from all 45 CFR part 46 requirements.

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Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

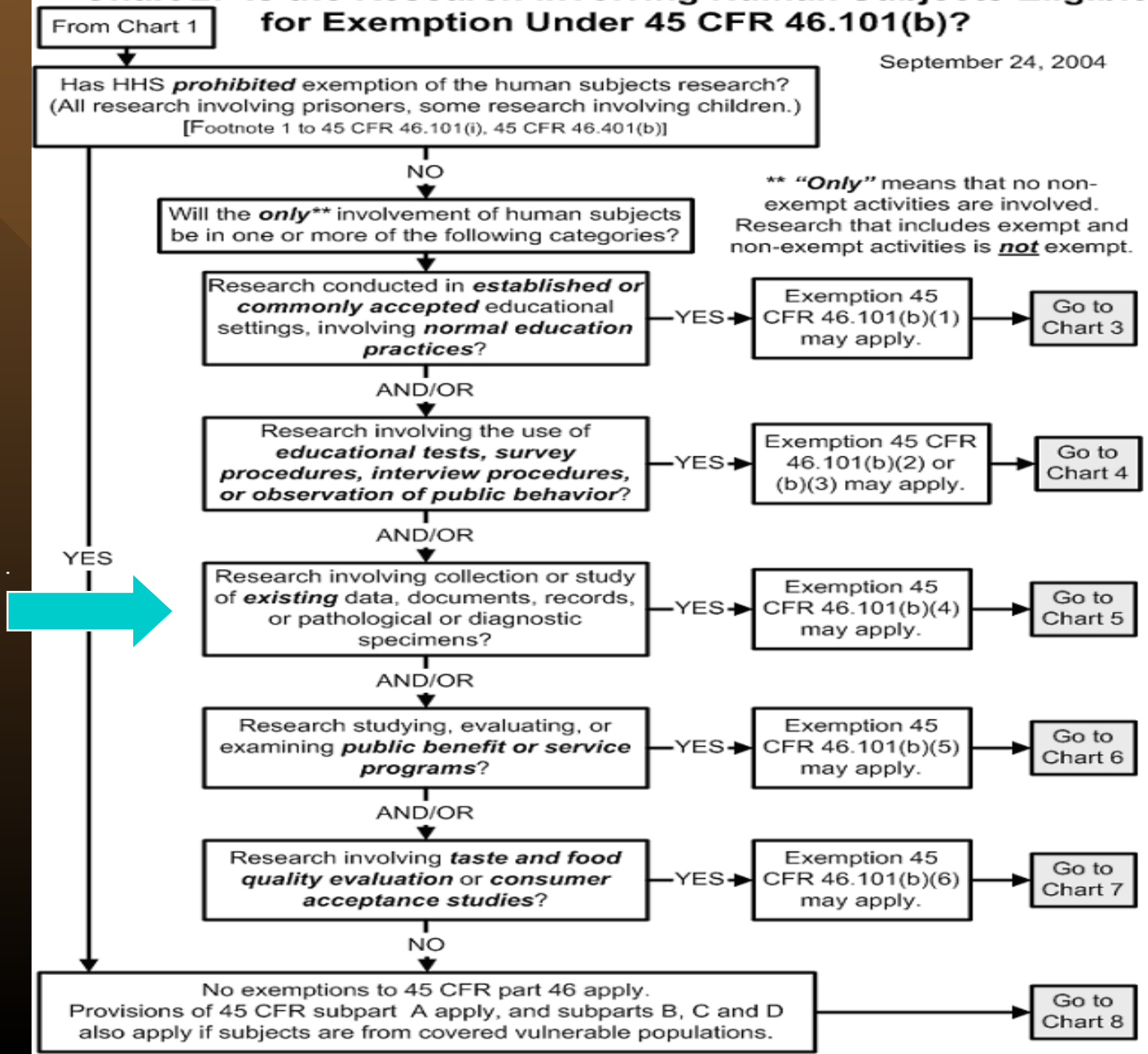
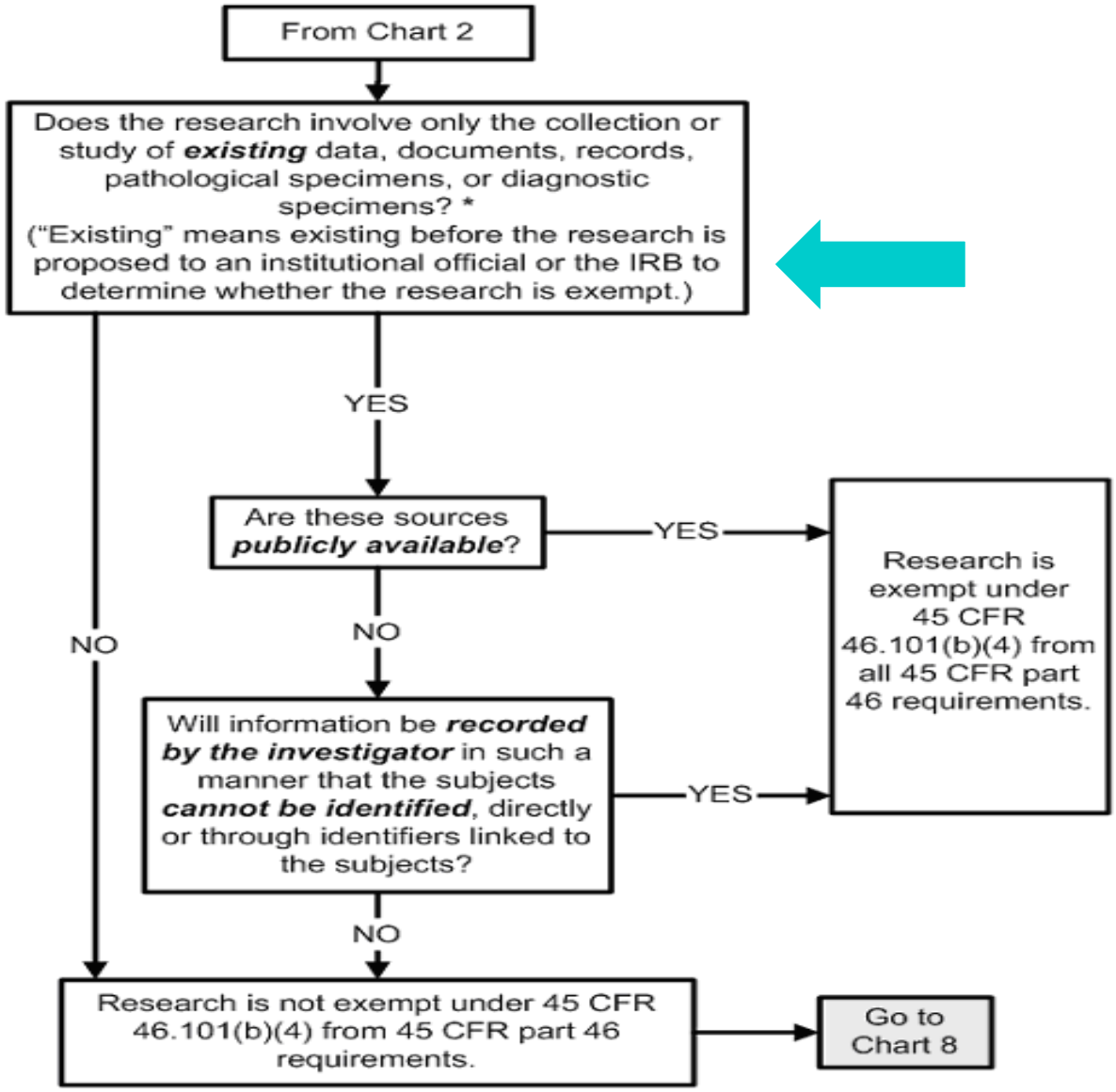

From Chart 1
September 24, 2004
Has HHS *prohibited* exemption of the human subjects research? (All research involving prisoners, some research involving children.) [Footnote 1 to 45 CFR 46.101(i), 45 CFR 46.401(b)]
NO
YES
** *"Only"* means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is ***not*** exempt.
Will the *only*** involvement of human subjects be in one or more of the following categories?
Research conducted in *established or commonly accepted* educational settings, involving *normal education practices*?
YES
Exemption 45 CFR 46.101(b)(1) may apply.
Go to Chart 3
AND/OR
Research involving the use of *educational tests, survey procedures, interview procedures, or observation of public behavior*?
YES
Exemption 45 CFR 46.101(b)(2) or (b)(3) may apply.
Go to Chart 4
AND/OR
Research involving collection or study of *existing* data, documents, records, or pathological or diagnostic specimens?
YES
Exemption 45 CFR 46.101(b)(4) may apply.
Go to Chart 5
AND/OR
Research studying, evaluating, or examining *public benefit or service programs*?
YES
Exemption 45 CFR 46.101(b)(5) may apply.
Go to Chart 6
AND/OR
Research involving *taste and food quality evaluation* or *consumer acceptance studies*?
YES
Exemption 45 CFR 46.101(b)(6) may apply.
Go to Chart 7
NO
No exemptions to 45 CFR part 46 apply. Provisions of 45 CFR subpart A apply, and subparts B, C and D also apply if subjects are from covered vulnerable populations.
Go to Chart 8

Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?


From Chart 2
Does the research involve only the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens? *
("Existing" means existing before the research is proposed to an institutional official or the IRB to determine whether the research is exempt.)
YES
NO
Are these sources publicly available?
YES
NO
Research is exempt under 45 CFR 46.101(b)(4) from all 45 CFR part 46 requirements.
Will information be recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects?
YES
NO
Research is not exempt under 45 CFR 46.101(b)(4) from 45 CFR part 46 requirements.
Go to Chart 8

* Note: See **OHRP** guidance on research use of stored data or tissues and on stem cells at http://www.hhs.gov/ohrp/policy/index.html#tissues and #stem, and on coded data or specimens at #coded for further information on those topics.

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But there is some confusion about the term ‘existing’

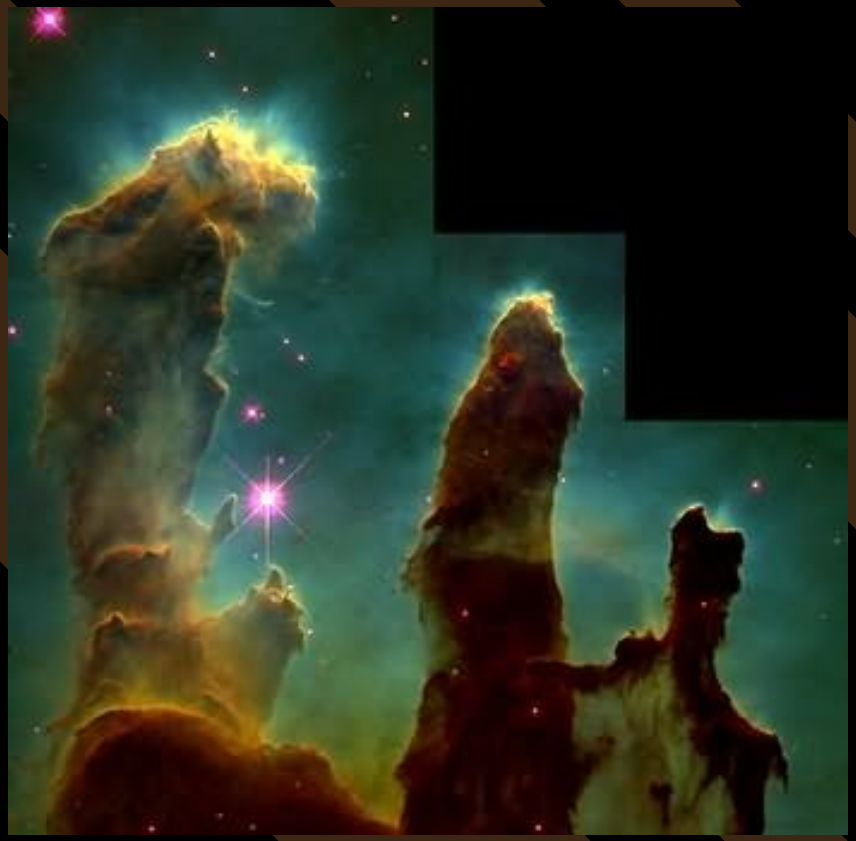
OHRP does not consider research involving **only** coded private information or specimens to involve human subjects as defined under 45 CFR46.102(f) if the following conditions are both met:

(1) the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and

(2) the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the

Who should determine whether you're doing human subjects research

OHRP recommends that institutions have policies in place that designate the individual or entity authorized to determine whether a research activity constitutes human subjects research. The person(s) authorized to make the determination should be knowledgeable about the human subject protection regulations. In addition, the institution should ensure the appropriate communication of such a policy to all investigators. OHRP recommends that investigators not be given the authority to make an independent determination. In the biomedical research community even exempt research is tracked. However, in this setting, where there has been long-term and well-understood 'accessions' research, all parties probably know what is and what



Questions?